JFW

PTO/SB/21 (02-04)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	10/735,991
Filing Date	12/15/2003
First Named Inventor	Goodnow et al.
Art Unit	1615
Examiner Name	Amy H. Bowman
Attorney Docket Number	21366 US1

Total Number of Pages in This Submission

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
- ☐ After Allowance communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to Group **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):

Remarks

Petition to the Director under 37 C.F.R. § 1.144 to Withdraw Examiner's Restriction Requirements, Exhibit A (22 pages) and Exhibit B (23 pages)

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Brian C. Remy
Signature	Brian Remy
Date	12/22/2005

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Typed or printed name	Brian C. Remy		
Signature	Brian Remy	Date	12/22/2005

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application

Goodnow et al.

Application No. 10/735,991, filed December 15, 2003

Confirmation No. 4512

Group: 1635

Examiner: Amy H. Bowman

For: **SEQUENCE #115 AS A TARGET FOR IDENTIFYING WEIGHT MODULATING COMPOUNDS**

PETITION TO THE DIRECTOR UNDER 37 C.F.R. § 1.144 TO WITHDRAW EXAMINER'S RESTRICTION REQUIREMENT

Nutley, New Jersey 07110
December 22, 2005

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants respectfully petition the Director under 37 C.F.R. § 1.144 for withdrawal of the Restriction Requirement issued May 12, 2005.

This petition is proper and timely because: (1) the Restriction Requirement was traversed and reconsideration was requested in a response filed on June 9, 2005; (2) the Restriction Requirement was made final on August 15, 2005; and (3) the petition is being submitted before a final action on or allowance of the claims. Pursuant to 37 C.F.R. § 1.144, a petition may be made at any time "until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal."

In accordance with 37 C.F.R. § 1.181, the following is a statement of the facts involved, points to be reviewed, and action requested.

I. Facts Involved

The instant application was filed on December 15, 2003 with 36 claims concerning "mammalian sequence #115" (a particular G protein coupled receptor including nucleotide sequences encoding the same) and its association with body weight. In the Restriction Requirement, the Examiner divided the invention into 14 separate Groups and required the Applicants to elect a single Group. A copy of the restriction requirement is attached hereto as **Exhibit A** showing the division of Groups.

The Examiner asserted that Groups I – XIV were distinct, each from the other for the reasons set forth in the Restriction Requirement and that to examine the application without restriction would impose an undue burden on the Examiner and the Patent Office resources.

The Applicants provisionally elected with traverse Group I in a response filed on June 9, 2005. The Applicants argued that they did not believe a serious burden existed for the Examiner to search and examine Groups I-XIV together since all of the Group were classified in the exact same class (514) and subclass (44).

According to the documents present in the image file wrapper, the Examiner submitted a search request to "STIC-Biotech/ChemLib" on June 28, 2005 to search **SEQ ID NO: 5** and received a list of results. In addition, according to the Search Notes available from the image file wrapper, a search was also conducted in WEST and Dialog using several search terms summarized in the attached queries. A copy of these documents is available from the image file wrapper.

On August 15, 2005, an Office Action was issued wherein the Examiner made the Restriction Requirement final and rejected the claims of Group I under 35 U.S.C. § 112 and 102. A copy of this Office Action is available from the image file wrapper.

On December 15, 2005, the Applicants filed a Reply & Amendment to the Office Action amending the claims including replacing the term "mammalian sequence #115" with **SEQ. ID NO: 6. SEQ ID. NO: 6** is an amino acid sequence of human "mammalian sequence #115." **SEQ ID NO: 5** (used by the Examiner in her search) is a nucleotide sequence encoding **SEQ ID NO: 6**. The Applicants also submitted a Supplemental Reply & Amendment on December 21, 2005, resubmitting two figures and the sequence listing to comply with the requirements of 37 C.F.R. 1.821-1.825, and to clarify the status of claims 35 and 36 as withdrawn. Copies of these papers are attached hereto as **Exhibit B**.

II. Points for Review

Is there an undue burden on the Examiner to rejoin and examine all or some of the 14 Groups together when all the Groups are all classified in the exact same class and subclass and there is little, if any, delineation among the Groups, and when the Examiner has already performed and presumably examined the results of a search that would cover and apply to all Groups.

A. All Groups Are Related And Classified In The Exact Same Class And Subclass

All the Groups listed by the Examiner are related and classified in the exact same class (514) and subclass (44). Moreover, there is little, if any, delineation among the Groups. Although the Examiner states that each of the inventions are unrelated because they have different modes of operations, different functions, or different effects, a review of the claims shows that that most, if not all, the claims are in fact related. All the claims (as amended) are related by **SEQ ID NO: 5** or

SEQ ID NO: 6 (**SEQ ID NO: 5** encodes **SEQ ID NO: 6**) (generically referred to as "mammalian sequence #115). The claims (as amended) are directed to methods of identifying compounds that modulate body weight (the method being based upon the nucleic acid sequence of **SEQ ID NO: 5** or amino acid sequence of **SEQ ID NO: 6**), compositions that contain such compounds identified by said method, methods of treatment using said compounds identified by said method, and antibodies that bind to **SEQ ID NO: 5** or **SEQ ID NO: 6**.

The Examiner asserts that the difference between Group I and II is that in Group I the method involves determining whether the test compound binds directly to the protein or nucleic acid and that in Group II the method involves determining whether the test compound alters the binding of a ligand to the protein or nucleic acid. Similarly, the asserted difference between Group I and Groups III-VII is that Groups III-VII involve contacting a test compound with a cell expressing the protein of Group I (in contrast to the protein itself) and determining whether the test compound alters the activity of the protein by measuring the level of some indicator (either cAMP, cytoplasmic Ca^{2+}, reporter gene, intracellular inositol 1,4,5-triphosphate, or intracellular 1,2-diaceylglyerol- which is the reason asserted by the Examiner of why Groups III-VII are unrelated). Likewise, the Examiner asserts that Groups I-VII are unrelated to Group VIII because Group VIII can be used in diagnostic or screening methods which don't involve modulating body weight - even though Group VIII is simply a pharmaceutical composition (or package in claim 18) containing a compound identified by the method of Group I. In addition, the Examiner asserts that Groups IX, X, XI, and XII are unrelated to the other groups and each other because they involve particular methods of treatment even though the methods all involve using the compounds identified by the methods of Groups I or II.

Other arguments made by the Examiner of why all 14 groups are independent, distinct and unrelated to each other are set forth in the Restriction Requirement (see **Exhibit A**). The Examiner

repeatedly asserts that to "search more then one of these inventions in the same application presents a search burden." However, these arguments and the reasoning presented by the Examiner in the Office Action requiring restriction appear illogical (please see **Exhibit A)**. Moreover, as stated above, all the Groups listed by the Examiner are classified in the exact same class (514) and subclass (44).

B. The Examiner Has Already Performed A Search Covering Most If Not All Groups

All the claims (as amended) are related by **SEQ ID NO: 6** or **SEQ ID NO: 5** (which encodes **SEQ ID NO: 6**).

According to the Examiner's search notes available from the image file wrapper, the Examiner has apparently already completed and reviewed a search based on a request to "STIC-Biotech/ChemLib" on June 28, 2005 to conduct a broad search on **SEQ ID NO: 5**. The Examiner has also conducted several searches using WEST and Dialog. A review of the search strategy used by the Examiner reveals that the search was not limited to any particular Group and apparently resulted in a reasonable number of records to review that covered and applied to most, if not all Groups.

Moreover, since all claims of the present invention (with the exception of antibody claims 35 & 36) have been amended to include the additional limitations of: (1) **SEQ ID NO: 6** (or nucleic acids encoding **SEQ ID NO: 6** such as **SEQ ID NO: 5**) and (2) the step of performing an in vivo assay to test the effect of the compound on body weight; a new search could be performed combining: (1) **SEQ ID NO: 6** (set to include nucleic acids encoding the same and set to include sequences with 85% or more homology and fragments of 8 or more amino acids- as claimed) with (2) terms such as "body weight," "obesity," or the like. The Applicants believe that such a search would be more than sufficient to cover all the Groups (with the exception of Groups 13-14 on

antibodies) which would result in a reasonable number of hits and which would not be an undue burden to review and examine. The Applicants are willing to accept the division of the antibody claims (claims 35 and 36).

C. Maintaining The Restriction Requirement Would Be Inequitable And Unfair To The Applicants

If the Restriction Requirement is maintained, the Applicants would have to file 14 different divisional applications. Using the current fee schedule, the Applicants would have to pay over $135,000.00 in filing-associated fees, issue fees and maintenance fees alone to prosecute, obtain, and maintain 14 divisional patents on all the pending claims in the current application. Moreover, this does not include the attorney and administrative costs involved in prosecuting and maintaining 14 divisional patent applications.

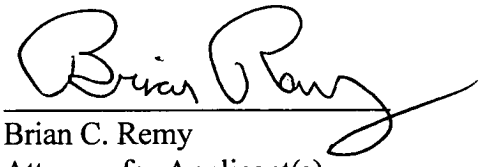
On the other hand, the Examiner would unjustly benefit by such an arrangement since the Examiner would acquire **28 counts** (credited to her employment performance) from a single application where the amount of work required is essentially the same as that required for a single application (**2 counts**). The Applicants believe that this is inequitable, unjust, and rises to the level of an abuse of the Examiner's power to restrict.

III. Action Requested

The Applicants respectfully request that the Director withdraw the Restriction Requirement issued May 12, 2005 and direct the Examiner to rejoin and examine all or at least most of the 14 Groups together in the present application.

It does not appear that there is any fee associated with the filing of this petition. However, the Director is hereby authorized to charge any deficit, or credit any overpayment, to Deposit Account No. 08-2525.

Respectfully submitted,



Brian C. Remy
Attorney for Applicant(s)
(Reg. No. 48,176)
340 Kingsland Street
Nutley, New Jersey 07110
Telephone: (973) 235-6516
Telefax: (973) 235-2363

164579

AAS/TSR I/GER

PETITION TO THE DIRECTOR TO WITHDRAW THE RESTRICTION REQUIREMENT UNDER 37 C.F.R. § 1.144 - EXHIBIT A

Exhibit A

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,991	12/15/2003	Robert Alan Goodnow JR.	21366 US1	4512

151 7590 05/12/2005

HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
340 KINGSLAND STREET
NUTLEY, NJ 07110

MAY 16

OIPE IAP15
DEC 27 2005
PATENT & TRADEMARK OFFICE

EXAMINER	
BOWMAN, AMY HUDSON	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Restriction
RESPONSE DUE: June 12, 2005

(3 mos.)
STATUTORY
PERIOD EXPIRES: Sept. 12, 2005

PTO-90C (Rev. 10/03)

Copy Sent to
Department PLP

Exhibit A

PETITION TO THE DIRECTOR TO WITHDRAW THE RESTRICTION REQUIREMENT UNDER 37 C.F.R. § 1.144 - EXHIBIT A *Office Action Summary*	Application No. 10/735,993	Applicant(s) GOODNOW ET AL.
	Examiner Amy H. Bowman	Art Unit 1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/15/2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3, 5, 14, 19, 25, 28, 30 and 33, drawn to a method for identifying compounds useful for modulating body weight, the method comprising contacting a test compound with a mammalian sequence #115 and identifying a compound that binds to the mammalian sequence #115, classified in class 514, subclass 44.

II. Claims 2, 4, 6, 15, 22, 26, 29, 31 and 34, drawn to a method for identifying compounds useful for modulating body weight, the method comprising contacting a sequence #115 ligand with a mammalian sequence #115 in the presence or absence of a test compound and identifying a compound that alters the binding of the sequence #115 ligand and the mammalian sequence #115, classified in class 514, subclass 44.

III. Claims 7, 8, 16, 27 and 32, drawn to a method for identifying compounds useful for modulating body weight, the method comprising contacting a test compound with a cell expressing a mammalian sequence #115 and identifying a compound that alters activity of the mammalian #115 sequence, wherein the activity of mammalian sequence #115 is determined by measuring the level of cAMP in the cell, classified in class 514, subclass 44.

IV. Claims 7, 9, 16, 27 and 32, drawn to a method for identifying compounds useful for modulating body weight, the method comprising contacting a test compound with a cell expressing a mammalian sequence #115 and identifying a compound that alters activity of the mammalian #115 sequence, wherein the activity of mammalian sequence #115 is determined by measuring the level of cytoplasmic Ca^{2+} in the cell, classified in class 514, subclass 44.

V. Claims 7, 10, 11, 16, 27 and 32, drawn to a method for identifying compounds useful for modulating body weight, the method comprising contacting a test compound with a cell expressing a mammalian sequence #115 and identifying a compound that alters activity of the mammalian #115 sequence, wherein the activity of mammalian sequence #115 is determined by measuring expression of a reporter gene, classified in class 514, subclass 44.

VI. Claims 7, 12, 16, 27 and 32, drawn to a method for identifying compounds useful for modulating body weight, the method comprising contacting a test compound with a cell expressing a mammalian sequence #115 and identifying a compound that alters activity of the mammalian #115 sequence, wherein the activity of mammalian sequence #115 is determined by measuring intracellular inositol 1,4,5-trisphosphate, classified in class 514, subclass 44.

VII. Claims 7, 13, 16, 27 and 32, drawn to a method for identifying compounds useful for modulating body weight, the method comprising contacting a test compound with a cell expressing a mammalian sequence #115 and identifying a compound that alters activity of the mammalian #115 sequence, wherein the activity of mammalian sequence #115 is determined by measuring intracellular 1,2-diacylgylcerol, classified in class 514, subclass 44.

VIII. Claims 17 and 18, drawn to a pharmaceutical formulation for the modulation of body weight comprising a compound that modulates the activity of a mammalian sequence #115,classified in class 514, subclass 44.

IX. Claim 20, drawn to a method of treating obesity comprising administering a pharmaceutical composition comprising a test compound that binds to mammalian sequence #115, classified in class 514, subclass 44.

X. Claim 21, drawn to a method of treating cachexia comprising administering a pharmaceutical composition comprising a test compound that binds to mammalian sequence #115, classified in class 514, subclass 44.

XI. Claim 23, drawn to a method of treating obesity comprising administering a pharmaceutical composition comprising a test compound alters the binding of the sequence #115 ligand to the mammalian #115 sequence, classified in class 514, subclass 44.

XII. Claim 24, drawn to a method of treating cachexia comprising administering a pharmaceutical composition comprising a test compound alters the binding of the sequence #115 ligand to the mammalian #115 sequence, classified in class 514, subclass 44.

XIII. Claim 35, drawn to an antibody that recognizes an isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 6, classified in class 514, subclass 44.

XIV. Claim 36, drawn to an antibody that recognizes an isolated polypeptide which is encoded by a nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO: 5.

The inventions are distinct, each from the other because of the following reasons:

The invention of group I is unrelated to the invention of group II. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different modes of operation. Although each of the groups are drawn to a method for identifying compounds useful for modulating body weight, each of the specific methods have different modes of operation. The method of group I comprises contacting a test compound with a mammalian sequence #115 and identifying a compound that binds to the mammalian sequence #115, whereas the method of group II comprises contacting a sequence #115 ligand with a mammalian

sequence #115 in the presence or absence of a test compound and identifying a test compound that alters the binding of the ligand. Group I does not involve the use of a ligand. A search for one of these inventions would not necessarily return art against the other invention, due to the differences in mode of operation. To search more than one of these inventions in the same application presents a search burden.

The invention of group I is unrelated to the inventions of groups III-VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different modes of operation. Although each of the groups are drawn to a method for identifying compounds useful for modulating body weight, each of the specific methods have different modes of operation. The method of group I comprises contacting a test compound with a mammalian sequence #115 and identifying a compound that binds to the mammalian sequence #115, whereas each of the methods of groups III-VII comprise contacting a test compound with a cell expressing a mammalian sequence #115 and identifying a compound that alters activity of the mammalian #115 sequence, further comprising measuring the level of cAMP, cytoplasmic Ca^{2+}, reporter gene, intracellular inositol 1,4,5-triphosphate, or intracellular 1,2-diacylglycerol. Group I merely involves binding to a mammalian sequence #115, rather than alteration of mammalian #115 activity. A search for one of these inventions would not necessarily return art against the other

invention, due to the differences in mode of operation. To search more than one of these inventions in the same application presents a search burden.

The inventions of groups I-VII are related to the invention of group VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the pharmaceutical formulation of group VIII can be used in a diagnostic or screening method, which does involve modulating body weight. Each of these inventions involve separate considerations and would require a separate search. To search one of the inventions would not necessarily return art against the other.

The invention of group I is unrelated to the inventions of groups IX, X, XI and XII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. The method of group I is drawn to identifying compounds useful for modulating body weight, wherein the methods of groups IX, X, XI and XII are drawn to treating obesity or cachexia. A search for group I would not involve treatment effects. A search for one of these inventions would not necessarily return art against the other invention, due to the differences in effects. To search more than one of these inventions in the same application presents a search burden.

The invention of group I is unrelated to the inventions of groups XIII and XIV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different functions. The method of group I is drawn to identifying compounds useful for modulating body weight, whereas groups XIII and XIV are drawn to antibodies. A search for group I would not involve the search for an antibody. A search for one of these inventions would not necessarily return art against the other invention, due to the differences in function. To search more than one of these inventions in the same application presents a search burden.

The invention of group II is unrelated to the inventions of groups III-VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different modes of operation. Although each of the groups are drawn to a method for identifying compounds useful for modulating body weight, each of the specific methods have different modes of operation. The method of group II comprises contacting a sequence #115 ligand with a mammalian sequence #115 in the presence or absence of a test compound and identifying a test compound that alters the binding of the ligand, whereas each of the methods of groups III-VII comprise contacting a test compound with a cell expressing a mammalian sequence #115 and identifying a compound that alters activity of the

mammalian #115 sequence, further comprising measuring the level of cAMP, cytoplasmic Ca^{2+}, reporter gene, intracellular inositol 1,4,5-triphosphate, or intracellular 1,2-diacylglycerol. Group II involves ligand binding to a mammalian sequence #115, rather than alteration of mammalian #115 activity. A search for one of these inventions would not necessarily return art against the other invention, due to the differences in mode of operation. To search more than one of these inventions in the same application presents a search burden.

The invention of group II is unrelated to the inventions of groups IX, X, XI and XII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. The method of group II is drawn to identifying compounds useful for modulating body weight, whereas the methods of groups IX, X, XI and XII are drawn to treating obesity or cachexia. A search for group II would not involve treatment effects. A search for one of these inventions would not necessarily return art against the other invention, due to the differences in effects. To search more than one of these inventions in the same application presents a search burden.

The invention of group II is unrelated to the inventions of groups XIII and XIV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not

disclosed as capable of use together and have different functions. The method of group II is drawn to identifying compounds useful for modulating body weight, whereas groups XIII and XIV are drawn to antibodies. A search for group II would not involve the search for an antibody. A search for one of these inventions would not necessarily return art against the other invention, due to the differences in function. To search more than one of these inventions in the same application presents a search burden.

The inventions of groups III-VII are each unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different modes of operation. Although each of the groups are drawn to a method for identifying compounds useful for modulating body weight, each of the specific methods have different modes of operation. The method of group III comprises determining the activity of mammalian sequence #115 by measuring the level of cAMP in the cell; group IV is drawn to determining the activity of mammalian sequence #115 by measuring the level of cytoplasmic Ca^{2+} in the cell; group V is drawn to determining the activity of mammalian sequence #115 by measuring expression of a reporter gene; group VI is drawn to determining the activity of mammalian sequence #115 by measuring intracellular inositol 1,4,5-trisphosphate; and group VII is drawn to determining the activity of mammalian sequence #115 by measuring intracellular 1,2-diacylglycerol. Each of these methods involve distinct mechanisms, each comprising an agent that is structurally distinct from each other. A search for one of these inventions

would not necessarily return art against the other invention, due to the differences in structure and mode of operation. To search more than one of these inventions in the same application presents a search burden.

The inventions of groups III-VII are each unrelated to the inventions of groups IX, X, XI and XII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. The methods of groups III-VII are drawn to identifying compounds useful for modulating body weight, whereas the methods of groups IX, X, XI and XII are drawn to treating obesity or cachexia. A search for any of the methods of groups III-VII would not involve treatment effects. A search for one of these inventions would not necessarily return art against the other invention, due to the differences in effects. To search more than one of these inventions in the same application presents a search burden.

The invention of groups III-VII are each unrelated to the inventions of groups XIII and XIV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different functions. The methods of groups III-VII are drawn to identifying compounds useful for modulating body weight, whereas groups XIII and XIV are drawn to antibodies. A search for the methods of groups III-VII would not involve the search for an antibody. A search for one of these

inventions would not necessarily return art against the other invention, due to the differences in function. To search more than one of these inventions in the same application presents a search burden.

The inventions of groups IX-XII are each related to the invention of group VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the pharmaceutical formulation of group VIII can be used in a diagnostic or screening method, which does involve preparing a pharmaceutical composition, or treating obesity or cachexia. Each of these inventions involve separate considerations and would require a separate search. To search one of the inventions would not necessarily return art against the other.

The invention of group VIII is unrelated to the inventions of groups XIII and XIV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different functions. Group VIII is drawn to a pharmaceutical formulation for modulation of body weight, whereas groups XIII and XIV are drawn to antibodies. A search for the pharmaceutical composition would not involve the search for an antibody. A search for one of these inventions would not necessarily return art against the other invention, due to the differences in function. To

search more than one of these inventions in the same application presents a search burden.

The inventions of groups IX and XI are unrelated to the inventions of groups X and XII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. The methods of groups IX and XI are drawn to treating obesity, whereas the methods of groups X and XII are drawn to treating cachexia. Obesity and cachexia are two distinct disorders, each having separate etiologies. To search for treating one of these disorders would not necessarily return art against the other invention, due to the differences in effects. To search more than one of these inventions in the same application presents a search burden.

The inventions of groups IX and XI are unrelated to the inventions of groups XIII and XIV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. The methods of groups IX and XI are drawn to treating obesity, whereas groups XIII and XIV are drawn to antibodies. To search for methods of treating obesity would not involve a search for the antibodies. To search for one of these inventions would not necessarily return art

against the other invention, due to the differences in effects. To search more than one of these inventions in the same application presents a search burden.

The invention of group IX is unrelated to the invention of group XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different modes of operation. Although the methods of groups IX and XI are each drawn to treating obesity, each of the methods involves a different mode of operation and different structural considerations. The methods of group IX comprises administering a pharmaceutical composition comprising a test compound that binds mammalian sequence #115, whereas the method of group XI comprises administering a pharmaceutical composition comprising a test compound that alters the binding of the sequence #115 ligand to the mammalian #115 sequence. A search for the method of group IX does not involve ligands. To search for one of these inventions would not necessarily return art against the other invention, due to the differences in mode of operation. To search more than one of these inventions in the same application presents a search burden.

The inventions of groups X and XII are unrelated to the inventions of groups XIII and XIV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. The methods of

groups X and XII are drawn to treating cachexia, whereas groups XIII and XIV are drawn to antibodies. To search for methods of treating cachexia would not involve a search for the antibodies. To search for one of these inventions would not necessarily return art against the other invention, due to the differences in effects. To search more than one of these inventions in the same application presents a search burden.

The invention of group X is unrelated to the invention of group XII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different modes of operation. Although the methods of groups X and XII are each drawn to treating cachexia, each of the methods involves a different mode of operation and different structural considerations. The methods of group X comprises administering a pharmaceutical composition comprising a test compound that binds mammalian sequence #115, whereas the method of group XII comprises administering a pharmaceutical composition comprising a test compound that alters the binding of the sequence #115 ligand to the mammalian #115 sequence. A search for the method of group X does not involve ligands. To search for one of these inventions would not necessarily return art against the other invention, due to the differences in mode of operation. To search more than one of these inventions in the same application presents a search burden.

The invention of group XIII is unrelated to the invention of group XIV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together

and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. Although the methods of groups XIII and XIV are each drawn to antibodies, each of the antibodies recognize an isolated polypeptide comprising a different amino acid sequence. Each of the sequences are unrelated and are considered separate and distinct inventions. Each of the sequences do not have a common structural core and therefore require a separate search. To search for one of the antibodies would not necessarily return art against the other antibody. To search more than one of these inventions in the same application presents a search burden.

Because the inventions are distinct for the reasons given above, and because a search for art against one group would not necessarily return art against another, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is

earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

This application contains claims directed to the following patentably distinct species of the claimed invention: Claim 11 contains multiple species of reporter genes.

Claim 11 is drawn to alkaline phosphatase, chloramphenicol acetyltransferase, luciferase, glucuronide synthetase, growth hormone, or placental alkaline phosphatase.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is 571-272-0755. The examiner can normally be reached on Mon-Fri 7:00 am – 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It

also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

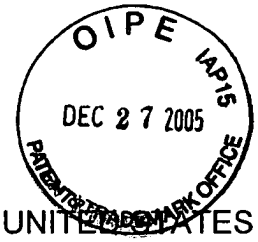
For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Amy H. Bowman
Examiner
Art Unit 1635

JAMES SCHULTZ
PATENT EXAMINER

Exhibit B

PETITION TO THE DIRECTOR
UNDER 37 C.F.R. § 1.144- EXHIBIT B



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application — Confirmation No. 4512

Goodnow et al. — Group: 1635

Application No. 10/735,991, filed December 15, 2003 — Examiner: Amy H. Bowman

For: **SEQUENCE #115 AS A TARGET FOR IDENTIFYING WEIGHT MODULATING COMPOUNDS**

REPLY & AMENDMENT

Nutley, New Jersey 07110
December 15, 2005

Mail Stop: Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

"A"

Dear Sir:

In response to the Office Action mailed August 15, 2005, the Applicants respectfully request that the following amendments and remarks be made of record in the above-identified application. Submitted herewith is a Petition for Extension of Time (in duplicate) accompanied by the appropriate provision authorizing payment of the required fee.

Amendments to the Specification begin on page 2 of this paper. Amendments to the Claims are reflected in the listing of claims which begin on page 3 of this paper. Remarks begin on page 10 of this paper.

PETITION TO THE DIRECTOR UNDER 37 C.F.R. § 1.144- EXHIBIT B

Exhibit B

Amendments To The Specification

Please replace paragraph [0008] on page 3 of the specification with the following replacement paragraph. Added matter relative to the previous version of the paragraph is indicated by underlining:

[0008] Fig. 4 depicts an alignment of human sequence #115 (SEQ. ID. NO: 5, referred to as "SEQUENCE_115_" in Fig. 4) with mouse sequence MOUSEGN:CHR7-36867 (SEQ. ID. NO: 1, referred to as "MOUSE_CHR7-36867" in Fig. 4).

Exhibit B

Amendments To The Claims

1. (Currently amended) A method for identifying compounds useful for modulating body weight, the method comprising:

A1

(a) contacting a test compound with: ~~a mammalian sequence #115~~(1) a protein having an amino acid sequence that is at least 85% identical to SEQ ID NO: 6 or a fragment thereof having at least 8 amino acids; or (2) a nucleic acid molecule encoding said protein;

(b) determining whether the test compound binds to ~~the mammalian sequence #115; and~~ said protein or nucleic acid molecule;

(c) if the test compound binds to said protein or nucleic acid molecule then administering the test compound to a mammal and measuring the effect of the test compound on the body weight of said mammal;

wherein if the body weight of said mammal is modulated after administration of the test compound then the test compound is ~~identifying a compound that binds to the mammalian sequence #115 as~~ a compound useful for modulating body weight.

2. (Withdrawn- currently amended) A method for identifying compounds useful for

A2

modulating body weight, the method comprising:

(a) contacting a ~~sequence #115~~ ligand with a ~~mammalian sequence #115~~ protein having an amino acid sequence that is at least 85% identical to SEQ ID NO: 6 or a fragment thereof having at least 8 amino acids in the presence and absence of a test compound;

(b) determining whether the test compound alters the binding of ~~the sequence #115 ligand to the mammalian sequence #115; and~~said ligand to said protein;

(c) if the test compound alters the binding of said ligand to said protein then administering the test compound to a mammal and measuring the effect of the test compound on the body weight of said mammal;

wherein if the body weight of said mammal is modulated after administration of the test compound then the test compound is~~identifying a compound that alters the~~

~~binding of the sequence #115 ligand to the mammalian sequence #115 as~~ a compound useful for modulating body weight.

A3 3. (Currently amended) The method of claim 1, wherein ~~the mammalian sequence #115~~the protein is expressed on the surface of a recombinant cell.

A4 4. (Withdrawn- currently amended) The method of claim 2, wherein the ~~mammalian sequence #115~~ the protein is expressed on the surface of a recombinant cell.

A5 5. (Currently amended) The method of claim 3, wherein the recombinant cell is a[n] eukaryotic cell.

A6 6. (Withdrawn- currently amended) The method of claim 4, wherein the recombinant cell is a[n] eukaryotic cell.

A7 7. (Withdrawn - currently amended) A method for identifying compounds useful for modulating body weight, the method comprising:

(a) contacting a test compound with a cell expressing a ~~mammalian sequence #115~~ a protein having an amino acid sequence that is at least 85% identical to SEQ ID NO: 6;

(b) determining whether the test compound alters the activity of ~~the mammalian sequence #115; and~~ said protein;

(c) if the test compound alters the activity of said protein then administering the test compound to a mammal and measuring the effect of the test compound on the body weight of said mammal;

wherein if the body weight of said mammal is modulated after administration of the test compound then the test compound is~~identifying a compound that alters activity of the mammalian sequence #115 as~~ a compound useful for modulating body weight.

A8 8. (Withdrawn - currently amended) The method of claim 7, wherein the activity of ~~mammalian sequence #115~~ the protein is determined by measuring the level of cAMP in the cell.

A9 9. (Withdrawn - currently amended) The method of claim 7, wherein the activity of ~~the mammalian sequence #115~~ the protein is determined by measuring the level of cytoplasmic Ca^{2+} in the cell.

A10 10. (Withdrawn) The method of claim 8, wherein the cell further contains a reporter gene operatively associated with a cAMP responsive element, and the level of cAMP is measured by measuring expression of the reporter gene.

A11 11. (Withdrawn) The method of claim 10, in which the reporter gene is alkaline phosphatase, chloramphenicol acetyltransferase, luciferase, glucuronide synthetase, growth hormone, or placental alkaline phosphatase.

A12 12. (Withdrawn - currently amended) The method of claim 7, wherein the activity of ~~the mammalian sequence #115~~ the protein is measured by measuring intracellular inosital 1,4,5-trisphophate (1P3).

A13 13. (Withdrawn - currently amended) The method of claim 7, wherein the activity of ~~the mammalian sequence #115~~ the protein is measured by measuring intracellular 1,2-diacylglycerol (DAG).

14. (Original) The method of claim 1, wherein the mammal is a mouse.

A14 15. (Withdrawn) The method of claim 2, wherein the mammal is a mouse.

A15 16. (Withdrawn) The method of claim 7, wherein the mammal is a mouse.

Exhibit B

17. (Withdrawn- currently amended) A pharmaceutical formulation for the modulation of body weight, comprising a compound ~~that modulates the activity of a mammalian sequence #115,~~ useful for modulating body weight identified by the method of claim 1 mixed with a pharmaceutically acceptable carrier.

18. (Withdrawn) A package comprising the pharmaceutical formulation of claim 17 and instructions for administering the pharmaceutical formulation for the purpose of modulating body weight.

19. (Currently amended) A method for preparing a pharmaceutical composition useful for modulating body weight, the method comprising:

(a) contacting a test compound with: ~~a mammalian sequence #115~~(1) a protein having an amino acid sequence that is at least 85% identical to SEQ ID NO: 6 or a fragment thereof having at least 8 amino acids; or (2) a nucleic acid molecule encoding said protein;

(b) determining whether the test compound binds to ~~the mammalian sequence #115~~ said protein or nucleic acid molecule;

(c) if the test compound binds to said protein or nucleic acid molecule then administering the test compound to a mammal and measuring the effect of the test compound on the body weight of said mammal; wherein if the body weight of said mammal is modulated after administration of the test compound then the test compound is a compound useful for modulating body weight; and

(d) combining the test compound ~~that binds to the mammalian sequence #115~~ useful for modulating body weight with a pharmaceutically acceptable carrier to create a pharmaceutical composition useful for modulating body weight.

20. (Withdrawn-currently amended) A method for the treatment of obesity comprising administering, to a patient in need thereof, the ~~pharmaceucitcal~~pharmaceutical composition according to claim 19 wherein the test compound decreases body weight.

21. (Withdrawn-currently amended) A method for the treatment of cachexia comprising administering, to a patient in need thereof, the ~~pharmaceucitcal~~pharmaceutical composition according to claim 19 wherein the test compound increases body weight.

22. (Withdrawn-currently amended) A method for preparing a pharmaceutical composition useful for modulating body weight, the method comprising:

(a) contacting a ~~sequence #115~~ ligand with a ~~mammalian sequence #115~~ protein having an amino acid sequence that is at least 85% identical to SEQ ID NO: 6 or a fragment thereof having at least 8 amino acids in the presence and absence of a test compound;

(b) determining whether the test compound alters the binding of ~~the sequence #115 ligand to the mammalian sequence #115; and~~said ligand to said protein;

(c) if the test compound alters the binding of said ligand to said protein then administering the test compound to a mammal and measuring the effect of the test compound on the body weight of said mammal; wherein if the body weight of said mammal is modulated after administration of the test compound then the test compound is~~identifying a compound that alters the binding of the sequence #115 ligand to the mammalian sequence #115 as~~ a compound useful for modulating body weight; and

(d) combining the test compound ~~that binds to the mammalian sequence #115~~ useful for modulating body weight with a pharmaceutically acceptable carrier to create a pharmaceutical composition useful for modulating body weight.

23. (Withdrawn-currently amended) A method for the treatment of obesity comprising administering, to a patient in need thereof, the ~~pharmaceucitcal~~pharmaceutical composition according to claim 22 wherein the test compound increases body weight.

24. (Withdrawn-currently amended) A method for the treatment of cachexia comprising administering, to a patient in need thereof, the

~~pharmaceucitcal~~pharmaceutical composition according to claim 22 wherein the test compound decreases body weight.

A24 25. (Currently amended) The method of claim 1, wherein ~~the mammalian sequence #115 is murine sequence #115~~ the test compound is contacted with the protein.

A25 26. (Withdrawn-currently amended) The method of claim ~~2~~1, wherein ~~the mammalian sequence #115 is murine sequence #115~~ the test compound is contacted with the nucleic acid molecule.

A26 27. (Withdrawn-currently amended) The method of claim 7, wherein ~~the mammalian sequence #115 is murine sequence #115~~ the protein has an amino acid sequence that is at least 95% identical to SEQ ID NO: 6.

A27 28. (Currently amended) The method of claim 19, wherein ~~the mammalian sequence #115 is murine sequence #115~~ the test compound is contacted with the protein.

A28 29. (Withdrawn-currently amended) The method of claim 22, wherein ~~the mammalian sequence #115 is murine sequence #115~~ the protein has an amino acid sequence that is at least 95% identical to SEQ ID NO: 6.

A29 30. (Currently amended) The method of claim ~~1~~2, wherein ~~the mammalian sequence #115 is human sequence #115~~ the test compound is contacted with the protein.

A30 31. (Withdrawn-currently amended) The method of claim 2, wherein ~~the mammalian sequence #115 is human sequence #115~~ the test compound is contacted with the nucleic acid molecule.

A31 32. (Withdrawn-currently amended) The method of claim 7, wherein ~~the mammalian sequence #115 is human sequence #115~~ the protein has an amino acid sequence that is at least 99% identical to SEQ ID NO: 6.

A32 33. (Currently amended) The method of claim 19, wherein ~~the mammalian sequence #115 is human sequence #115~~ the test compound is contacted with the nucleic acid molecule.

A33 34. (Withdrawn-currently amended) The method of claim 22, wherein ~~the mammalian sequence #115 is human sequence #115~~ the protein has an amino acid sequence that is at least 99% identical to SEQ ID NO: 6.

35. (Original) An antibody that recognizes an isolated polypeptide comprising the amino acid sequence of SEQ ID NO:6.

36. (Original) An antibody that recognizes an isolated polypeptide which is encoded by a nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:5.

REMARKS

The specification has been amended to include the required SEQ ID NO: identifiers in the brief description of FIG. 4 as requested by the Examiner.

Claims 1-9, 12-13, and 19-34 have been amended. The amendments do not constitute new matter and are fully supported by the original claims, the sequence listing, and the specification. Specifically, support for the above amendments can be found in the specification on p. 1, paragraph [0001], p. 3, paragraph [0009], and p. 4, paragraph [0010] (supporting the additional limitation of administering the test compound to a mammal in a separate in vivo assay measuring the effect of the test compound on the body weight of the mammal); pp. 16-17, paragraph [0042] (supporting the limitation of contacting a test compound with a protein or nucleic acid molecule encoding a protein having an amino acid sequence at least about 85%, 95%, 96%, 97%, 98%, or 99% identical to the amino acid sequence of mammalian sequence #115 - SEQ ID NO: 6); pp. 4-7, paragraphs [0010], [0011], [0013], [0016], [0017], p. 12, paragraph [0030], and p. 29, paragraph [0070] (supporting the limitation of a protein fragment of mammalian sequence #115 - SEQ ID NO: 6- having at least 8 amino acids). Claims 2, 4, 6-13, 15-18, 20-24, 26, 27, 29, 31, 32 and 34-36 have been withdrawn by the Examiner as non-elected. Thus, claims 1, 3, 5, 14, 19, 25, 28, 30, 33, and 35-36 are pending.

The Applicants expressly rebut any presumption that the Applicants have surrendered any equivalents under the doctrine of equivalents and expressly state that the claims, as amended, are intended to include and encompass the full scope of any equivalents as if the claims had been originally filed and not amended. If the Examiner disagrees or does not examine the claims (including considering any prior art) with the understanding that the amended claims include and encompass the full scope of all equivalents under the doctrine of equivalents as if the claims had been originally filed, the Applicants respectfully request that the Examiner note this on the record in writing. Otherwise, the Examiner agrees that any such presumption has been rebutted by the

understanding that such claims include and encompass the full scope of all equivalents under the doctrine of equivalents as if the claims had been originally filed and not amended.

I. Restriction Requirement

The Examiner notes that she has considered the Applicants arguments in response to the restriction requirement but nonetheless deems the restriction requirement proper. As a consequence, the Examiner has made the restriction requirement final withdrawing claims 2, 4, 6-13, 15-18, 20-24, 26, 27, 29, 31, 32, and 34-36 as nonelected inventions. The Applicants continue to respectfully disagree with the Examiner's restriction requirement and plan to petition the Director under 37 C.F.R. § 1.144 under separate cover for the rejoinder of Groups I-XIV.

II. Sequence Compliance

The Examiner states that the application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because there are sequences in FIG. 4 that do not contain a SEQ ID NO. In response, the specification has been amended to include the required SEQ ID NO: identifiers in the brief description of FIG. 4 as requested by the Examiner.

III. Claim Rejections Under 35 USC § 112, Indefiniteness

Claims 1, 3, 5, 14, 19, 25, 28, 30 and 33 are rejected under 35 U.S.C. § 112, first paragraph, for indefiniteness. The Examiner states that it is unclear what "mammalian sequence #115" means (i.e., polypeptide or polynucleotide). In response, the Applicants have clarified the claims by the above amendments and replaced the term "mammalian sequence #115" with SEQ. ID NO: 6. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

IV. Claim Rejections Under 35 USC § 112, Written Description

Claims 1, 3, 5, 14, 19, 25, 28, 30 and 33 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that due to the lack of clarity with respect to the term "mammalian sequence #115," the skilled artisan would not be able to recognize that the applicant was in possession of the claimed invention at the time of filing. In response, the Applicants have amended the claims to address the Examiner's concerns and replaced the term "mammalian sequence #115" with SEQ. ID NO: 6. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

V. Claim Rejections Under 35 USC § 112, Enablement

Claims 1, 3, 5, 14, 19, 25, 28, 30 and 33 are rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner asserts that the specification does not reasonably provide enablement for a method of making and using the claimed invention. According to the Examiner, the specification does not teach a link between a compound's ability to bind mammalian sequence #115 and the modulation of body weight, nor has any teaching in the prior art been located that describes such a link. The Examiner further asserts that "due to the lack of guidance in the specification as filed, as well as in the prior art, regarding how identifying a test compound that binds to mammalian sequence #115 would impact modulation of body weight, there is no perceived correlation between binding mammalian sequence #115 and modulation of body weight."

In response, the Applicants note that the claims have been amended to include the additional limitation of performing an in vivo assay to test the effect of the compound on body weight. Accordingly, the invention is not directed to methods of identifying compounds that bind to mammalian sequence #115 as compounds that necessarily modulate body weight per se; but rather, the invention is directed to methods of

identifying (or pre-selecting) compounds that bind to mammalian sequence #115 as compounds to further screen or test in separate in vivo assays to determine their effect on body weight.

One of the utilities of the claimed invention is that it narrows down the number of compounds to screen or test with regard to body weight modulating activity. Part of the novelty and unobviousness of the present invention lies in the discovery that the expression level of the G-protein coupled receptor- mammalian sequence #115 (as exemplified by the SEQ ID NOS of the present invention)- is altered by changes in body weight. Therefore, compounds that bind to mammalian sequence #115 (as exemplified by the SEQ ID NOS of the present invention) by their very nature (in light of the novel discovery of the present invention) become primary candidates or leads to test in separate in vivo assays to determine whether they modulate body weight. Thus, the claimed invention is, in essence, directed to novel research methods of screening compounds that modulate body weight.

Contrary to the Examiner's assertion, there is a reasonable correlation between body weight and the expression of mammalian sequence #115 (as exemplified by the SEQ ID NOS of the present invention). For instance, Example 4 and Figure 3 show that the expression of murine sequence #115 (sequenced and identified in Figure 4 as "MOUSEGN_CHR7-36867") was altered in diet induced obese mice. In fact, several alterations occurred. Specifically, a 1.6 fold decrease occurred in the expression of mRNA of this gene in obese mice vs. control mice in the arcuate nucleus region of the brain and ventromedial hypothalamus region of the brain; and more significantly, a 5 fold decrease occurred in the expression of mRNA in obese mice vs. control mice in the posterior pituitary region of the brain. Expression levels were also altered in other areas of the brain in obese mice vs. control mice as shown in Figure 3.

Thus, the claims (as amended) are fully enabled by the specification. Accordingly, the Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, for lack of enablement be withdrawn.

VI. Claim Rejections Under 35 USC § 102(b), Glucksmann

Claims 1, 3, 5, 14, 19, 25, 28, 30 and 33 are rejected under 35 U.S.C. § 102(b) as anticipated by Glucksmann et al (WO 99/37679). The Examiner asserts that Glucksmann teaches methods of identifying compounds that bind and modulate the expression of a G-protein coupled receptor (flh2882). According to the Examiner, the flh2882 DNA sequence is 1728 nucleotides long and is 99.7% identical with SEQ ID NO: 5 where it overlaps with SEQ ID NO: 5.

In response, the Applicants note that Glucksmann does not disclose all the elements of the claims as amended. In order for a reference to anticipate a claim under 35 U.S.C. § 102, the reference must disclose every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference." See MPEP § 2131.

Glucksmann fails to disclose any correlation or relationship of the flh2882 gene or protein with the modulation of body weight. All the rejected claims of the present invention have been amended to include the additional limitation of performing an in vivo assay to test the effect of the compound on body weight. This limitation is not disclosed or suggested by Glucksmann (either expressly or inherently).

Accordingly, because Glucksmann fails to disclose all the elements of each claim expressly or inherently, the rejection under 35 U.S.C. § 102 should be withdrawn.

Exhibit B

VII. Claim Rejections Under 35 USC § 102(a) & 102(e), Liaw

Claims 1, 3, 5, 14, 19, 25, 28, 30 and 33 are rejected under 35 U.S.C. § 102(a) or 102(e) as anticipated by Liaw et al (WO 02/068600). The Examiner asserts that Liaw teaches methods of identifying compounds that bind and modulate the expression of a G-protein coupled receptor. According to the Examiner, Liaw teaches a DNA sequence that is 1014 nucleotides long and is 98.3% identical to SEQ ID NO: 5.

In response, the Applicants note that Liaw does not disclose all the elements of the claims as amended. In order for a reference to anticipate a claim under 35 U.S.C. § 102, the reference must disclose every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference." See MPEP § 2131.

Liaw fails to disclose any correlation or relationship of Liaw's G-protein coupled receptor with the modulation of body weight. All the rejected claims of the present invention have been amended to include the additional limitation of performing an in vivo assay to test the effect of the compound on body weight. This limitation is not disclosed or suggested by Liaw (either expressly or inherently).

Accordingly, because Liaw fails to disclose all the elements of each claim expressly or inherently, the rejection under 35 U.S.C. § 102 should be withdrawn.

VIII. Conclusion

Entry of the foregoing remarks and amendments is respectfully requested. No fee is believed to be due in connection with the filing of this Amendment, other than the fee for the Petition For Extension of Time. However, if any other fee is deemed necessary, authorization is given to charge the amount of any such fee to Deposit Account No. 08-2525.

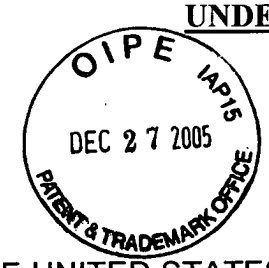
Respectfully submitted,

Attorney for Applicant(s)
Brian C. Remy
(Reg. No. 48176)
340 Kingsland Street
Nutley, NJ 07110
Telephone (973) 235-6516
Telefax: (973) 235-2363

162962

Exhibit B

PETITION TO THE DIRECTOR
UNDER 37 C.F.R. § 1.144- EXHIBIT B



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application

Goodnow et al.

Application No. 10/735,991, filed December 15, 2003

Confirmation No. 4512

Group: 1635

Examiner: Amy H. Bowman

For: **SEQUENCE #115 AS A TARGET FOR IDENTIFYING WEIGHT MODULATING COMPOUNDS**

SUPPLEMENTAL REPLY & AMENDMENT

Nutley, New Jersey 07110
December 21, 2005

Mail Stop: Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Further to the Reply & Amendment filed on December 15, 2005 in response to the Office Action mailed August 15, 2005, the Applicants respectfully request that the following supplemental amendments and remarks be made of record in the above-identified application. Submitted herewith is: (1) replacement sheets for Figures 1 and 2; (2) paper copies of substitute sheets containing the substitute Sequence Listing; (3) a replacement computer readable diskette containing the substitute Sequence Listing; and (4) a Statement for the submission of the substitute Sequence Listing pursuant to 37 C.F.R. § 1.821 – 1.825.

Amendments to the Drawings begin on page 2 of this paper. Amendments to the Sequence Listing begin on page 3 of this paper. Remarks begin on page 4 of this paper.

PETITION TO THE DIRECTOR UNDER 37 C.F.R. § 1.144- EXHIBIT B

Exhibit B

Amendments To The Drawings

Please replace the drawing sheets labeled "FIG. 1: SEQ ID NO:1" and "FIG. 2: SEQ ID NO: 2" with the attached replacement sheets of drawings, labeled "Replacement Sheet" in accordance with 37 C.F.R. § 1.121(d).

FIG. 1 is being replaced because it incorrectly depicts the human nucleic acid sequence of mammalian sequence #115 when it should depict the mouse sequence. Likewise, FIG. 2 is being replaced because it incorrectly depicts the human amino acid sequence of mammalian sequence #115 when it should depict the mouse sequence. The replacement drawings (FIG. 1 AND FIG. 2) show the correct mouse nucleic acid and amino acid sequences of mammalian sequence #115, respectively.

The replacement drawings do not constitute new matter because the correct mouse nucleic acid coding sequence of mammalian sequence #115 is disclosed in FIG. 4 (as originally filed; referred to as "MOUSE_CHR7-36867" in FIG. 4) which encodes (and therefore discloses) the correct mouse amino acid sequence of mammalian sequence #115.

PETITION TO THE DIRECTOR UNDER 37 C.F.R. § 1.144- EXHIBIT B

Exhibit B

Amendments To The Sequence Listing

Please replace the paper copy of the Sequence Listing with the attached substitute sheets containing the substitute Sequence Listing and please replace the computer readable diskette of the Sequence Listing with the enclosed replacement computer readable diskette containing the substitute Sequence Listing.

The Sequence Listing is being replaced because SEQ ID NO: 1 incorrectly depicts the human nucleic acid sequence of mammalian sequence #115 when it should depict the mouse sequence. Likewise, SEQ ID NO:2 is being replaced because it incorrectly depicts the human amino acid sequence of mammalian sequence #115 when it should depict the mouse sequence. Thus, the substitute Sequence Listing depicts the correct mouse sequence for SEQ ID NO:1 and SEQ ID NO: 2. The remaining SEQ ID NOS. are the same as those originally filed.

The substitute sheets and replacement computer readable diskettes of the Sequence Listing do not contain new matter because SEQ ID NO: 1 is disclosed in FIG. 4 (as originally filed; referred to as "MOUSE_CHR7-36867" in FIG. 4) which encodes (and therefore discloses) the amino acid sequence of SEQ ID NO: 2.

REMARKS

Figure 1 and Figure 2 (showing SEQ ID NO:1 and SEQ ID NO: 2 respectively) have been replaced in accordance with 37 C.F.R. § 1.121(d). In addition, SEQ ID NO:1 and SEQ ID NO: 2 in the Sequence Listing (both paper copy and computer readable form) have been replaced in accordance with 37 C.F.R. § 1.825.

The Applicants discovered that SEQ ID NO:1 and SEQ ID NO: 2 (as filed) depict the human nucleic acid and human amino acid sequences of mammalian sequence #115 respectively when such sequences should depict the mouse (mus musculus) sequences.

As stated above, the replacement Figures and substitute Sequence Listing do not constitute new matter because the correct mouse nucleic acid sequence for SEQ ID NO: 1 is disclosed in FIG. 4 (as originally filed; referred to as "MOUSE_CHR7-36867" in FIG. 4) which encodes (and therefore discloses) the correct mouse amino acid sequence of SEQ ID NO: 2 as well. The remaining sequences are the same as originally filed.

Also enclosed herewith is the required Statement for the submission of the substitute Sequence Listing pursuant to 37 C.F.R. § 1.821 – 1.825.

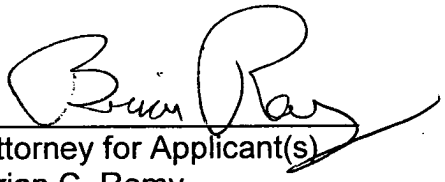
Additionally, after filing the Reply & Amendment on December 15, 2005, the Applicants realized that the status of claims 35 and 36 in the attached listing of claims was incorrect. Claims 35 and 36 have been withdrawn by the Examiner. Therefore, the status indicated in the parenthetical next to claims 35 and 36 should read "withdrawn" (not "original"). The Applicants will submit a new claim listing with this correction if required by the Examiner.

PETITION TO THE DIRECTOR UNDER 37 C.F.R. § 1.144- EXHIBIT B

Exhibit B

Entry of the foregoing supplement reply and amendment is respectfully requested. No fee is believed to be due in connection with the filing of this supplemental reply and amendment. However, if any such fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 08-2525.

Respectfully submitted,



Attorney for Applicant(s)
Brian C. Remy
(Reg. No. 48176)
340 Kingsland Street
Nutley, NJ 07110
Telephone (973) 235-6516
Telefax: (973) 235-2363

215847